

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

JOSIE C. KO,

Plaintiff,

v.

MUTUAL PHARMACEUTICAL  
COMPANY, INC.,

Defendant.

Case No. C-13-00890-RMW

**ORDER GRANTING DEFENDANT  
MUTUAL PHARMACEUTICAL'S  
MOTION TO DISMISS**

[Re Docket Nos. 8 and 21]

Plaintiff Josie C. Ko brings state-law products liability claims against defendant Mutual Pharmaceutical Company, alleging injuries caused by defendant's product sulindac, a generic anti-inflammatory medication. Mutual moves to dismiss for failure to state a claim, or in the alternative, on the basis that Ko's claims are preempted. Mutual also moves to strike Ko's response to the motion to dismiss. As explained below, the court GRANTS Mutual's motion to dismiss.

**I. BACKGROUND**

On January 17, 2013, plaintiff Josie C. Ko, proceeding *pro se*, filed a form complaint in the Santa Clara County Superior Court, alleging "products liability" for injuries suffered following her prescribed use of sulindac, a generic anti-inflammatory medication manufactured by defendant Mutual Pharmaceutical Company. Compl. 1, Dkt. No. 1, Ex. 1. On the form complaint, Ko stated

that she had suffered "internal heart organ failure—myocarditis—due to prescribed sulindac medication." *Id.* at 2. Ko did not attach any causes of action to the form complaint, nor did she give any other description of her injuries.

On February 27, 2013, Mutual removed the case to federal court on the basis of diversity jurisdiction.<sup>1</sup> Notice of Removal ¶¶ 7-9, Dkt. No. 1. On March 6, 2013, Mutual filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). Mot. Dismiss, Dkt. No. 8. Subsequently, on April 19, Ko filed a response to the motion to dismiss signed by her husband, Antonio C. Ko, that contains an "Attachment to Complaint and Demand for Jury Trial," and a "Declaration in Support of Opposition to Motion," as well as several other attachments and exhibits that elaborate on the original complaint. Pl.'s Resp., Dkt. No. 20. On April 26, 2013, Mutual filed a motion to strike this response. Mot. Strike, Dkt. 21.

## II. ANALYSIS

Mutual moves to strike Ko's opposition and dismiss the entire complaint. However, the court first notes that "the allegations of a *pro se* litigant's complaint are to be held to less stringent standards than formal pleadings drafted by lawyers." *Castro v. U.S.*, 540 U.S. 375, 386 (2003) (quoting *Haines v. Kerner*, 404 U.S. 519, 520 (1972)). Furthermore, "*pro se* litigants do not lose their right to a hearing on the merits of their claim due to ignorance of technical procedural requirements." *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990).

### A. Motion to Strike

Mutual argues that Ko's entire response to the motion to dismiss violates Rule 11(a) of the Federal Rules of Civil Procedure, because it was signed and submitted by Ko's husband, who is neither a party to the action nor an attorney authorized to represent Ko. Mutual also argues that Ko's "Attachment to Complaint and Demand for Jury Trial" contained in the response to the motion to dismiss is an untimely amendment to the original complaint, in violation of Federal Rule of Civil Procedure 15(a).

<sup>1</sup> The court is satisfied that the diversity jurisdiction requirements of 28 U.S.C. § 1332(c)(1) have indeed been met, as plaintiff Ko is a citizen of California, defendant Mutual is incorporated in Delaware with its principal place of business in Pennsylvania, and Ko seeks relief in the amount of \$2 million. Removal ¶ 6-9, Dkt. No. 1.

Rule 11(a) states that "[e]very pleading, written motion, and other paper must be signed by at least one attorney of record in the attorney's name—or by a party personally if the party is unrepresented." Fed. R. Civ. P. 11(a). Furthermore, "[t]he court must strike an unsigned paper unless the omission is promptly corrected after being called to the attorney's or the party's attention." *Id.* See also 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1333 (3d ed. 2004) ("[T]he Rule 11 signature requirement is not satisfied when a non-lawyer signs a paper on behalf of an unrepresented party"); *Johns v. Cnty. of San Diego*, 114 F.3d 874, 876 (9th Cir. 1997) ("a non-lawyer 'has no authority to appear as an attorney for others than himself.'") (quoting *C.E. Pope Equity Trust v. United States*, 818 F.2d 696, 697 (9th Cir.1987)). As Ko's husband is neither a party nor an attorney authorized to represent her, his signature does not satisfy the signature requirement of Rule 11(a). While ordinarily the court would give Ko an opportunity to correct this error, other defects, addressed below, obviate the need to correct the signature.

Mutual also argues that the "Attachment to Complaint" contained in the response to the motion to dismiss is untimely. The "Attachment to Complaint" contains some of the information that ought to have been included in the original complaint, namely, Ko's causes of action and a slightly more detailed account of the injuries she has suffered. However, Ko filed this document outside the 21-day period in which Ko could have amended her complaint as a matter of course under Rule 15(a)(1). Ko also could have asked the court for leave to amend, or sought Mutual's written permission to amend, pursuant to Rule 15(a)(2), but did not do so. Again, the court might ordinarily allow Ko to correct this error, but even if the court considered the attachment part of the complaint, the complaint would still fail on the merits as explained in the next section.

## **B. Motion to Dismiss**

Mutual asserts two main arguments in support of its motion to dismiss. First, Ko's complaint fails to state a claim showing that she is entitled to relief. Second, any claim Ko might present is preempted by federal law under the U.S. Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

### 1. Failure to state a claim

Ko's complaint fails to satisfy the pleading standards of Federal Rule of Civil Procedure 8(a). The Rule requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In order to survive a motion to dismiss, the facts pled in the complaint, taken as true, must allow the court "to draw the reasonable inference that defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 663. "While a complaint...does not need detailed factual allegations...a formulaic recitation of a cause of action's elements will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007); *see also Hargis v. Washington Mutual Bank*, No. C10-02341 CRB, 2011 WL 724390 (N.D. Cal. Feb. 22, 2011) (applying plausibility standard to complaint where case was removed from state court).

Here, Ko's complaint, without the improper amendments, contains little more than "threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Id.* at 555. The form complaint states only that Ko is suing Mutual for "products liability," without stating a specific cause of action, and provides only the barest factual allegations as to Ko's injuries ("internal heart organ failure—myocarditis") or the circumstances under which she took Mutual's drug ("by prescription"). Compl. 1. Most importantly, Ko's complaint contains no facts relating to the most crucial element of any products liability tort action: causation. The mere statement that she took sulindac, and then at some unspecified time later, suffered myocarditis, is not enough to raise her claim above the "speculative" level, as required under the *Twombly* and *Iqbal* plausibility standard. *Id.* at 545.

If Ko signed and the court considered the "Attachment to Complaint" and the "Declaration in Support of Opposition" all part of a validly amended complaint, Ko's pleading still would be inadequate. Ko asserts several claims against Mutual in the "Attachment to Complaint": strict liability, negligence, and breach of express and implied warranties. Some of the claims are still insufficient under Rule 8, and those that would survive are preempted. The court considers each below.

a. Strict liability

In order to establish a products liability claim based on a theory of strict liability, Ko need only assert that she was harmed by a product manufactured by Mutual that contained a manufacturing, design, or warning defect. *Greenman v. Yuba Power Products, Inc.*, 59 Cal. 2d 57, 62-63 (1963); *see also Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 995 (1991). In the "Attachment to Complaint" Ko's husband asserts that she was harmed by sulindac, a product manufactured by Mutual, and that "adequate warnings to primary physician were not provided." Attach. Compl. 1. In other words, she asserts that the product contained a warning defect. Furthermore, the "Declaration in Support of Opposition" states that Ko was prescribed sulindac because she was "experiencing pain...in her right hand," and that approximately 21 days after she started taking the medication, she experienced a high fever and broke out in rashes. A. Ko Decl. 1, Dkt. No. 20. Ko's husband further states that Ko was hospitalized ten days later for five days, and then again a month later, at which point she was diagnosed with myocarditis. *Id.* at 1-2. Finally, he summarily concludes that the necrosis of tissues in her heart were caused by sulindac. *Id.* at 2.

These allegations satisfy the plausibility pleading standard for a claim based on strict liability, since it is certainly plausible that Ko could prove at trial that she took sulindac and was subsequently harmed by it. However, as explained more fully below, federal law preempts state law failure-to-warn claims. Thus, Ko's strict liability warning defect claim must be dismissed, and Ko has not asserted any other facts in her complaint that might constitute a plausible claim based on a manufacturing or design defect.

b. Negligence

To assert a claim for negligence, Ko must allege that Mutual was negligent in designing, manufacturing, or labeling the product (creating a warning defect), and that this negligence was a substantial factor in causing Ko's harm. *Merrill v. Navegar, Inc.*, 26 Cal. 4th 465, 478-79 (2001). For this cause of action, however, Ko's allegations do not adequately state a claim. Neither the "Attachment to Complaint" nor the "Declaration in Support of Opposition" allege any facts suggesting that Mutual was in fact *negligent* in producing its product, or that this negligence was the cause of Ko's injuries. Again, Ko only asserts that Mutual did not provide adequate warning to her

1 physician. Adequate warning about what, precisely, is not clear. However, even if this statement  
 2 alone were enough to plausibly suggest negligence on Mutual's part, the warning defect claim is  
 3 preempted.

4 c. Breach of express and implied warranties

5 To the extent that Ko is asserting claims for breach of implied warranty of fitness and  
 6 implied warranty of merchantability, she has not alleged any facts that plausibly suggest Mutual's  
 7 product was somehow unsuited for its intended purpose (presumably, use as an anti-inflammatory).  
 8 *See Keith v. Buchanan*, 173 Cal. App. 3d 13, 25 (1985) (explaining that "an implied warranty of  
 9 fitness arises...when a seller has reason to know any particular purpose for which the goods are  
 10 required and that the buyer is relying on the seller's skill or judgement to select...goods...fit for  
 11 such purpose") (internal quotation marks omitted). Likewise, Ko has not alleged any facts that  
 12 suggest the product was un-merchantable because it did not conform to quality standards. *See Burr*  
 13 *v. Sherwin Williams Co.*, 42 Cal. 2d 682, 694 (1954) (explaining that "merchantable quality" refers  
 14 to goods "reasonably suitable for the ordinary uses...of goods of the general type...and which are  
 15 capable of passing in the market under the name or description by which they were sold"). To the  
 16 extent that Ko is claiming breach of an express warranty, this claim is preempted, given that the  
 17 only information Mutual is allowed to put on its label is prescribed by federal regulations (*see* 21  
 18 U.S.C. 355(j)), and as explained in the next section, Ko would thus be raising a state-law claim that  
 19 impermissibly conflicted with federal law.

20 **2. Preemption**

21 Mutual urges the court to dismiss with prejudice, arguing that Ko's claims are preempted by  
 22 the Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Because generic  
 23 drug manufacturers are required by federal law to use the same FDA approved labeling as the  
 24 manufacturers of the brand-name drug, and because generic manufacturers cannot legally change  
 25 their labels even to add additional warnings, any state-law claims based on failure-to-warn would  
 26 conflict impermissibly with federal FDA regulations, and are therefore preempted. *Id.* at 2570; *see*  
 27 *also Mutual Pharm. Co. v. Bartlett*, No. 12-142 (U.S. June 24, 2013) (reaffirming *Mensing* and  
 28 finding that state-law design-defect claims based on inadequate warnings are also preempted). To

1 the extent that Ko's claims are based on a failure-to-warn theory, including her claims for strict  
2 liability, negligence, and breach of express and implied warranties, these claims would indeed be  
3 preempted. *See Gaeta v. Perrigo Pharm. Co.*, No. 09-15001, 2012 WL 605678 (9th Cir. 2012),  
4 *aff'g* 562 F. Supp. 2d 1091 (N.D. Cal. 2008) (granting summary judgement in favor of defendant  
5 because plaintiff's state-law claims for negligence, breach of express warranty, and breach of  
6 implied warranty based on inadequate warning were preempted); *see also Phelps v. Wyeth, Inc.*, 857  
7 F. Supp. 2d 1114, 1123-24 (D. Or. Apr. 24, 2012) (holding that all warnings-based claims, including  
8 claims for negligence, strict liability, and breach of warranty are preempted); *Moretti v. PLIVA, Inc.*,  
9 No. 08-00396 2012 WL 62850 (D. Nev. Feb. 27, 2012) (holding that state-law claims for strict  
10 liability, negligence, breach of express and implied warranties based on inadequate warning are  
11 preempted).

12 However, because the complaint is ambiguous and *pro se* complaints are held to less rigid  
13 standards, the court will grant Ko the opportunity to amend her complaint.

### 14 III. ORDER

15 Mutual's motion to dismiss for failure to state a claim is GRANTED, and Ko's complaint is  
16 dismissed, without prejudice. Ko is given thirty days (by July 31, 2013) in which to amend her  
17 complaint, if she can do so in good faith.

18  
19  
20 Dated: July 1, 2013

  
RONALD M. WHYTE  
United States District Judge